



Advanced Medical Systems, Inc.

1020 London Road
Cleveland, OH 44110
(216) 692-3270

August 15, 1990

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

RE: Advanced Medical Systems, Inc., License No. 34-19089-01
Response to Notice of Violation

To Whom It May Concern:

I have consulted with our management team and offer the following responses to the three (3) areas requested to be addressed on Page Three of Mr. Davis' July 26, 1990 letter as well as the Notice of Violation:

I. RESPONSE TO ITEMS LISTED ON PAGE THREE OF MR. DAVIS' LETTER DATED JULY 26, 1990

- A. As a result of the January, 1990 inspection and resultant violations, AMS has taken several steps to evaluate and enhance management abilities regarding license activities. A special Isotope Committee Meeting and several Management Meetings were held in the month following the inspection to identify and discuss the causes of the violations noted by the NRC. The AMS Management Team has subsequently been tasked with performing an in-depth review of the AMS license and procedures. The purpose of this is to accomplish the following:
- 1.) Identify and correct any procedural deficiencies which could potentially result in a violation of regulatory requirements.
 - 2.) Eliminate conflicting or obsolete license conditions so that the license will remain comprehensive, yet will be easier to follow.
 - 3.) Identify and correct any deficient or obsolete procedures to reflect the improved conditions and practices.
 - 4.) Ensure that current practices are in compliance with regulatory requirements and license conditions.
 - 5.) Enhance management awareness of all aspects of the AMS license as well as the requirements of 10 CFR Parts 19, 20, and 30.

A license amendment request was submitted on July 23, 1990 which included several revised procedures and a request to delete several obsolete items. AMS views this request as a first step toward accomplishing the goals listed above. It is hoped that this and future requests and correspondence will demonstrate to the NRC AMS' increased Team Management abilities and involvement.

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B&C. AMS is considering periodic internal audits of license activities. These audits would be performed by management personnel other than the RSO. It is anticipated that these audits would be performed quarterly and the results would be brought to the attention of the RSO for discussion and action during Management and/or Isotope Committee Meetings. AMS realizes that although the general condition of the London Road facility and performance of license activities has improved in recent years, the continuation of this trend will not be possible without continued attention to detail. To fully address and implement the items mentioned in Items B and C, AMS is developing a new procedure to be submitted as part of our next amendment request.

II. AMS' RESPONSE TO NOTICE OF VIOLATION

A. The failure of the emergency generator to start apparently resulted from a combination of battery age and condition. Although corrective actions were taken prior to the failure, they proved insufficient. Corrective actions and dates completed are as follows:

- 1.) January 29, 1990: Inspection and test of charging system.
- 2.) February 28, 1990: Installed a new maintenance-free battery.
- 3.) May 7, 1990: Performed tune-up of generator. This included installing new ignition parts.

ISP-13 has been revised to provide a more comprehensive battery check and procedural requirement for noting defects and performing necessary corrective action. This procedure was submitted as part of a license amendment request on July 23, 1990.

B. (1) AMS previously obtained bioassay services from Perry Nuclear Power Plant. During 1989-early 1990, AMS unsuccessfully attempted to negotiate a continuation of these services. Following the March, 1990 Enforcement Conference, it was determined that Perry would no longer perform bioassays. The AMS Director of Regulatory Affairs then contacted Dr. Bruce Mallett of NRC Region III and received a list of facilities performing bioassays. AMS then reached an agreement with Presbyterian University Hospital of Pittsburgh, Pennsylvania. Presbyterian Hospital scheduled and performed the bioassays on July 31, 1990. Presbyterian Hospital has expressed a willingness to continue providing these services to AMS.

(2) At the time of occurrence, the AMS RSO was unaware of the procedural requirement for a special bioassay for greater than 40 MPS hours/week. Following analysis, it was determined that no regulatory limits were exceeded; and based on this, no decision for a special bioassay was made. The individual in question had a bioassay performed on July 31, 1990 indicating a body burden of approximately 7.2 nCi. (The official reports have not been received at the time of this response.) Through discussions with Mr. John Madera of NRC Region III during the January, 1990 inspection and subsequent Management Team and Isotope Committee Meetings, the RSO and Management Team have achieved a more thorough understanding of both license and regulatory requirements. AMS has received, and greatly appreciated,

the advice and assistance of Mr. Madera in pointing out areas of the bioassay program which need to be revised. A revised bioassay program will be submitted as part of a future amendment request.

(3) One individual did, in fact, have a bioassay performed upon termination of employment. However, repeated attempts to obtain a copy of the bioassay report have failed. A second individual terminated employment without notice and AMS was unable to arrange for bioassay services. At the time, AMS' Notification Letter was sent by First Class Mail. See Attachment A. AMS has revised its standard employee notification letters to require written notice if the employee declines or refuses bioassay services as arranged by AMS. Further, notification letters are now sent via Certified Mail to provide documentation of AMS' actions. See, e.g., Attachments B and C. Bioassay services are now arranged as described in B(1) above.

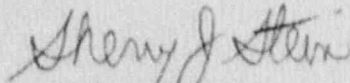
- C. The Decon Room lock, which had been replaced following an external audit in 1989, proved to be inadequate. The lock was replaced on January 26, 1990. The new lock assembly cannot be left unlocked and requires a key for each entry. This lock does not lock from the inside, thus allowing for exit at all times without the need for a key. This new lock has proved to be satisfactory.
- D. The alarming dosimeter was used in addition to several other methods and controls for monitoring exposure. Since cell openings and/or entries are infrequent, this additional dosimeter was checked to ensure it was operable prior to use although it was not sent out for calibration. All meters and instruments not in current use are now labeled as requiring calibration prior to use and stored in an area separate from those calibrated instruments currently in use. ISP-14 has been revised to delete the requirement for alarming dosimeters since AMS has instituted more effective methods and controls for monitoring and reducing personnel exposure. ISP-14 was submitted as part of a license amendment request on July 23, 1990.
- E. As discussed during the March, 1990 Enforcement Conference, AMS' letter of July 23, 1986 intended that physical inventory mean a decay of activity, not the actual removal and counting of each individual source. The practice of an accounting type of inventory was carried over from the previous licensee; and as it was not questioned in previous inspections, AMS felt there was no need to change its method of inventory. Since the January inspection, AMS has identified the location of several sources by physical observation. AMS is currently seeking buyers for many of the AMS sources stored in the garden as well as continuing to physically verify source locations. Should AMS be unsuccessful in selling a majority of these sources, we will request a meeting with the NRC to determine a feasible method of performing radioactive material inventories.
- F. At the time of occurrence, the AMS RSO was not aware of the regulatory requirement for specific documentation. Air sample logs, MPC records, and RWP records had previously been considered to be sufficient documentation. AMS has since recognized the requirements and is taking action as described in B(2) above to strengthen its bioassay program to meet these requirements.

August 15, 1990

- G. AMS employees had been under the impression that once submitted, the revised Management Plan, which included the new audit frequencies, was in effect. Through discussions with the NRC, AMS personnel now realize that final NRC approval is required prior to a new or revised license issue becoming effective. The new Management Plan, which calls for semi-annual audits, was approved in License Amendment No. 17.
- H. Although described as operational in the ISP-1 Manual, which was carried over from the previous licensee, the basement door light was apparently never actually installed. This item was not mentioned in previous inspections; it was first discussed during the January, 1990 inspection. A new light was installed over the basement door and in the alarm panel on February 26, 1990 and operates as described in the ISP-1 Manual. ISP-5 has been revised to accurately reflect the status and daily checks of the alarm board lights. This change was submitted July 23, 1990.
- I. The previous method of posting proved inadequate for high wind conditions as demonstrated by the fact that a new sign had been installed prior to the inspection on December 6, 1989. Following the inspection, a new boundary and sign was installed on February 8, 1990. The new boundary is physically anchored to the roof and has proved to be capable of withstanding high winds.

As always, should you have any questions or require any further clarification, please do not hesitate to contact me.

Sincerely,



SHERRY J. STEIN
Director of Regulatory Affairs

SJS/mz
Enclosures

cc: A. Bert Davis, Regional Administrator, Region III

CERTIFIED MAIL #P228723979
RETURN RECEIPT REQUESTED

April , 1989

Name
Address
Address

Dear

Upon the resignation of any employee who has worked in areas of radioactivity, Advanced Medical Sytems, Inc. requires a whole-body scan for radioactive burden. Our records indicate that although several attempts have been made by phone to arrange for your personal scan at the Perry Nuclear Power Plant, you have not been examined. AMS will make the arrangements to have this work completed by _____ . You have basically three (3) options:

1. Provide AMS with the whole-body scan information which may have been completed prior to your employment, immediately after resigning from AMS.
2. Contact _____ at (216) 692-3270 to make arrangements for this work.
3. Refuse your right to have this examination, thus releasing AMS from any and all responsibility associated with your AMS employment history.

We strongly urge you to exercise Option No. 2. However, AMS must complete its records by _____, 199__. Therefore, immediate action is required.

Sincerely,

SHERRY J. STEIN
Director of Regulatory Affairs

SJS/mz



Advanced Medical Systems, Inc.

121 North Eagle Street • Geneva, Ohio 44041
(216) 466-4671 TWX 810-4272-183

July 16, 1990

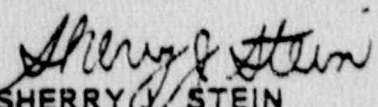
Mr. Edmond DeRosa
[REDACTED]
[REDACTED]

Dear Ed:

Please be advised that arrangements have been made for your annual bioassay at Presbyterian University Hospital, DeSoto Street, Pittsburgh, Pennsylvania on July 31, 1990. The group will depart from Geneva at 8:00 a.m. and will return at the completion of the final bioassay.

Please notify us in writing if you wish to make alternative arrangements at your own expense. If we do not hear from you, we will presume that you plan on joining the group on the 31st of July.

Sincerely,


SHERRY STEIN
Director of Regulatory Affairs

SJS/mz

CERTIFIED MAIL #P015168717
RETURN RECEIPT REQUESTED

August 8, 1990

Name
Address
Address

Dear

Upon the resignation of any employee who has worked in areas of radioactivity, Advanced Medical Systems, Inc. requires a whole-body scan for radioactive burden. Our records indicate that although several attempts have been made by phone to arrange for your personal scan at the Presbyterian University Hospital, you have not been examined. AMS will make the arrangements to have this work completed by _____ . You have basically three (3) options:

- 1.) Provide AMS with the whole-body scan information which may have been completed prior to your employment, immediately after resigning from AMS.
- 2.) Contact _____ at (216) 692-3270 to make arrangements for this work.
- 3.) Refuse your right to have this examination, thus releasing AMS from any and all responsibility associated with your AMS employment history.

We strongly urge you to exercise Option No. 2. However, AMS must complete its records by _____, 199____. Therefore, immediate action is required. Should you decide to choose Option 1 or 3, please notify me in writing no later than _____, 199____ of your decision.

Sincerely,

SHERRY J. STEIN
Director of Regulatory Affairs

SJS/mz

CERTIFIED MAIL #
RETURN RECEIPT REQUESTED